

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)	MDL No.1456
AVERAGE WHOLESALE PRICE)	Master File No. 01-CV-12257-PBS
LITIGATION)	Subcategory No. 06-CV-11337-PBS
)	
THIS DOCUMENT RELATES TO:)	Judge Patti B. Saris
<i>United States of America ex rel. Ven-A-Care of</i>)	
<i>the Florida Keys, Inc. v. Boehringer</i>)	
<i>Ingelheim Corporation, et al.</i> , Civil Action No.)	
07-10248-PBS)	
)	

UNITED STATES' OPPOSITION TO DEFENDANTS
BOEHRINGER INGELHEIM CORPORATION'S AND BOEHRINGER INGELHEIM
PHARMACEUTICAL INC.'S MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

Defendants Boehringer Ingelheim Corporation (“BIC”), Roxane’s parent company, and Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”), a Roxane sibling company, have moved for summary judgment, claiming that they are not liable to the United States because the drugs at issue (“Subject Drugs”) are all “Roxane drugs.” Their motion should be denied for two reasons. First, there is extensive evidence that BIC and BIPI actively participated in decisions to set inflated AWPs for the Subject Drugs and, therefore, are directly liable under the False Claims Act (“FCA”), 31 U.S.C. § 3729. BIC and BIPI employees knowingly assisted with – and frequently supervised – sales and marketing efforts for Roxane’s drugs, including by approving proposed AWPs for the Subject Drugs. BIPI employees provided input on the “very favorable Pharmacy spread” in Roxane’s pricing proposals and marketing plans. BIC and BIPI’s argument that they are not responsible for *their own employees’* conduct because such employees were acting as “agents” of Roxane fails because most of the employees in question were employed *only* by BIC or BIPI and, in any event, acted within the scope of that employment when approving Roxane’s pricing and marketing strategies.

Second, the evidence shows that BIC managed Roxane and BIPI as part of a single business unit, and that defendants ignored the corporate identities of Roxane and BIPI in managing their respective businesses. In addition to having overlapping management, Roxane and BIPI shared several core business functions, such as a common “Trade Relations” department responsible for promoting both companies’ products to wholesalers and other key customers. In addition, Roxane and BIPI coordinated marketing efforts, including jointly bidding

“bundles” of Roxane and BIPI products to important customers, and offering rebates on BIPI drugs that were contingent on customers’ commitment to purchase Roxane drugs as well. Most tellingly, in late 2002, after receiving a subpoena from the federal government relating to this case, Roxane paid an unbudgeted \$320 million “dividend” to BIC. The payment of this dividend marked a substantial departure from Roxane’s past practices, and left Roxane under-capitalized with liabilities more than five times larger than its total equity. In these circumstances, a triable issue exists as to whether Roxane operated as an independent corporation, and whether Roxane’s corporate form should be disregarded for reasons of fairness, equity, and the public convenience.

II. BACKGROUND

BIC, BIPI and Roxane are part of the Boehringer Ingelheim worldwide group of companies which, during the relevant time frame, was among the twenty largest pharmaceutical companies in the world. (United States’ Response to Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc. Statement of Material Facts (“US Resp. To BI SOF”), ¶ 1.) BIC is a holding company, and is the sole shareholder of Roxane, BIPI, and several other affiliated Boehringer Ingelheim entities in the United States. (Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc. Statement of Material Facts (“BI SOF”), ¶¶ 1-2.) Boehringer Ingelheim documents describe BIC as having “limited corporate functions,” and identify BIPI as the “primary operating company” for Boehringer Ingelheim’s United States operations. (US. Resp. To BI SOF, ¶ 2.) BIPI sells primarily branded drugs, and its employees performed various “corporate” functions on behalf of other Boehringer Ingelheim entities (including Roxane), such as legal, finance and administration, and human resources. (*Id.*) Roxane sells primarily multi-source pharmaceutical products. At various points

in time, Roxane sold many of its products as “branded generics,” meaning that even though the product was multi-source, Roxane marketed it under a brand name. (*Id.*, ¶ 16.)

The composition of the BIC and BIPI Boards of Directors was virtually identical throughout the relevant time period. (*Id.*, ¶ 4.) The BIC and BIPI Boards met regularly, including at joint BIC/BIPI Board meetings from 1996 through at least 2003. (*Id.*) Roxane business was frequently discussed at such meetings. (*Id.*) The Roxane Board of Directors met rarely (if ever) and, instead, acted through “unanimous written consents.” (*Id.*, at ¶ 22.) The Roxane Board was described as “not an active board” and “more to form than anything else” by the only Board member deposed in this litigation. (*Id.*)

A. Roxane and BIPI Were Managed As Part of a Single “Business Unit”

Beginning in at least 1994, Boehringer Ingelheim managed the Roxane and BIPI businesses as part of a common “Business Unit Ethical Pharmaceuticals” (sometimes referred to as the “Business Unit”). (*Id.*, ¶¶ 7-9, 51, 53.) The Business Unit was directed by Sheldon Berkle, who was employed as a Vice President at BIC and BIPI, but who was *not* an employee of Roxane.¹ (*Id.*) “In order to create a unified management” for the Business Unit, several Roxane employees, including Ed Tupa (Vice President, Sales and Marketing) and Fred Duy (Vice President, Business Planning and Development), reported “functionally” to Mr. Berkle. (*Id.*) Periodic changes were made to the structure of the Business Unit, including the creation of a unified pricing process for BIPI and certain Roxane products, and the merging of the Roxane and BIPI contracts departments into a single organization. (*Id.*, ¶¶ 7, 53.) From at least 1998 through

¹ Mr. Berkle was at various times a member of Roxane’s Board of Directors, but was never an employee or officer of Roxane. He was, however, an officer of both BIC and BIPI. (U.S. Resp. to BI SOF, ¶ 7.)

2001, Mr. Berkle and Tom Russillo supervised Roxane's branded generic and multi-source marketing efforts, yet neither was employed by Roxane (Mr. Russillo was employed by Ben Venue Laboratories, a Boehringer Ingelheim entity which is not a defendant in this case). (*Id.*)

Several Roxane employees in sales and marketing reported to their "BIPI counterparts." (*Id.*, ¶ 14, 51, 53.) For example, Gregg Ciarelli was employed by BIPI but served as "Marketing Controller" for the entire Business Unit. (*Id.*, ¶ 14) In that capacity, Mr. Ciarelli oversaw various Roxane employees, and Mr. Ciarelli also had "ongoing responsibility" for reporting prices (including AWPs) to third-party pricing compendia for Roxane's branded generic products. (*Id.*) In addition, Mr. Berkle identified Mr. Ciarelli as one of two persons responsible for ensuring that BIPI and Roxane complied with applicable laws in reporting prices. (*Id.*) Likewise, Jim King and Mike Leonetti were BIPI employees, but supervised Roxane's branded generic sales force and the Business Unit's Trade Relations Department, respectively. (*Id.*, ¶¶ 8, 14.) Other BIPI employees who assisted Roxane's sales and marketing efforts include James Rowenhorst, who recommended "focus[ing] on higher AWP and WAC" as a way of competing in the respiratory market, and Robert Sykora, who trained Roxane's palliative care sales force on Medicaid reimbursement and other matters.² (*Id.*, ¶¶ 8, 53, 75.)

Roxane and BIPI cooperatively marketed both companies' drugs to customers, including through the submission of joint bids of Roxane/BIPI product "bundles." (*Id.*, ¶ 9.) Rebates on BIPI products were often contingent on the customer committing to purchase products from all

² Mr. Sykora testified that although he "technically" was an employee of BIPI, he spent most of his time promoting Roxane products. Mr. Ciarelli, Mr. King, Mr. Leonetti, and Mr. Rowenhorst all testified that they were employed (and paid) by BIPI and BIPI only, but had responsibilities for supervising Roxane personnel. (U.S. Resp. to BI SOF, ¶¶ 8, 14.)

Boehringer Ingelheim entities, including Roxane. (*Id.*) Moreover, Roxane and BIPI pursued a “combined marketing strategy” for certain respiratory drugs, including ipratropium bromide, which is the generic version of BIPI’s Atrovent product. (*Id.*, ¶ 7.) Boehringer Ingelheim “preempted” generic competition for Atrovent by arranging for Roxane to launch its generic ipratropium bromide product while Atrovent was still patent-protected. (*Id.*) Although this strategy “cost” BIPI “a lot of money” in lost Atrovent sales, it was considered to be in the interest of the overall Boehringer Ingelheim group of companies. (*Id.*) Consistent with this strategy, Jim King advised BIPI’s sales force that “if Roxane’s ipratropium bromide is sold, or if an Atrovent solution is sold, you get credit for it.” (*Id.*) Likewise, Roxane was permitted to substitute Atrovent for ipratropium bromide orders when it ran into supply problems. (*Id.*)

B. BIC and BIPI Approved Roxane’s Pricing

BIC and BIPI exercised control over the pricing of Roxane’s products, including setting AWPs for the Subject Drugs. For example, a common “Pricing Policy and Procedure” was applicable both to BIPI products and to Roxane’s branded generic products (including Subject Drugs Roxicodone, Oramorph SR, and Roxanol). (*Id.*, ¶¶ 51, 75.) Pursuant to this policy, recommended prices (including AWPs) for Roxane’s branded generic products required approval first by a pricing committee, comprised jointly of Roxane and BIPI personnel, and then by the “Executive Vice President, Ethical Pharmaceuticals” (Mr. Berkle) and the “President and CEO, Boehringer Ingelheim Corporation” (Werner Gerstenberg). (*Id.*)

The August 2000 launch of Roxane’s 15 and 30 mg Roxicodone tablets (which are Subject Drugs, NDCs 00054-4658-25 and 00054-4665-25) demonstrates the extent of BIC and BIPI’s involvement in approving inflated AWPs for Roxane products. Consistent with his

general practice, Fred Duy (Roxane's Director of Business Development) emailed the Roxicodone launch plan and pricing proposal to Mr. Berkle and others on August 12, 2000. (*Id.*) The launch plan recommended setting AWPs twice as high as WACs in order to create "favorable retail reimbursement." (*Id.*) No fewer than five BIPI employees were involved in the decision to approve the Roxicodone pricing. On August 14, for example, Christine Ferrara (a BIPI employee who managed the Business Unit's pricing process) questioned the calculation of "the average spread to [p]harmacy," causing Mr. Duy to adjust the proposal accordingly. (*Id.*) On August 18, Mr. Leonetti (BIPI's Director of Managed Care) commented on the marketing plan, including the "very favorable pharmacy spread." (*Id.*) On August 22, the Pricing Committee (including BIPI employees Ferrara, Ciarelli, Leonetti and King) recommended approval of the proposed pricing, which it described as "compatible with the reimbursement model that drives retailer profit." (*Id.*) Shortly thereafter, the pricing was approved by Mr. Berkle (as head of the Business Unit) and Mr. Gerstenberg (as President and CEO of BIC). (*Id.*)

BIC and BIPI also participated in pricing decisions for Roxane's "multi-source" pricing. As noted above, BIPI assisted with Roxane's marketing strategies for ipratropium bromide. Specifically, several BIPI employees attended a January 1996 meeting where it was agreed that the AWP for itratropium bromide was to be 10% less than Atrovent (approximately \$44), compared to an expected selling price of \$21. (*Id.*, ¶¶ 7, 53, 68.) The ipratropium bromide launch plan explained that this pricing structure was used to "entice" customers to purchase the product. (*Id.*) Mr. Tupa (then Roxane's Vice President of Marketing) testified that he believed Boehringer Ingelheim officials, including Mr. Berkle, approved the launch plan. (*Id.*)

Boehringer Ingelheim officials also were consulted on Roxane multi-source pricing issues

regarded as “sensitive” or likely to raise “legal” issues, including decisions to raise AWPs. For example, in August 2000, Roxane raised the AWPs on furosemide by as much as 300%. (*Id.*, ¶¶ 30, 53, 61, 70-71.) Tom Russillo, who was at the time in charge of Roxane’s multi-source marketing, reported to Werner Gerstenberg “in his role as president and CEO of BIC.”³ (*Id.*, ¶¶ 30, 71.) Mr. Russillo testified that as of at least 1999, he and members of Boehringer Ingelheim’s senior management knew that the government was scrutinizing inflated AWPs and that defendants therefore regarded any decision to raise AWPs as “sensitive.” (*Id.*, ¶¶ 53, 61, 70-71.) Based on “many conversations” with Mr. Gerstenberg, Mr. Russillo understood his position to be that Roxane could raise AWPs to levels far in excess of sales prices, so long as Roxane was doing so to “match” competitors’ AWPs. Mr. Russillo testified that he would not have endorsed the AWP increase unless he thought it was authorized. (*Id.*)

The decision to raise the furosemide AWPs was not finalized until approval was obtained from Boehringer Ingelheim. Emails from July 2000 show that Mr. Russillo was prepared to “champion” and “support” the furosemide AWP increase, and take the proposal “up the line,” provided it was supported by “competitive” information. (*Id.*) In July 2000, Mr. Russillo advised his staff that “to get the approval we need from” Boehringer Ingelheim, “hard info” was required about competitors’ AWPs. (*Id.*) On July 26, 2000, Mr. Sykora submitted a “sales justification” and, shortly thereafter, Mr. Russillo received the “official okay to implement the [F]urosemide price changes.” (*Id.*)

³ Unlike Messrs. King, Ciarelli, Leonetti, Rowenhorst, etc. (all of whom were *only* BICI employees), Mr. Gerstenberg was an officer of Roxane as well as BIC. Mr. Russillo testified that he reported to Mr. Gerstenberg in his role as President and CEO of BIC, however, and continued to do so *after* Mr. Gerstenberg stepped down as President of Roxane. (U.S. Resp. to BI SOF, ¶¶ 30, 71.)

C. 2005 Reorganization

Several employees recognized that in the wake of organizational changes made to the Business Unit in the 1990s, Roxane and BIPI had become “kind of a intermingled company.” (*Id.*, ¶ 12.) Other employees expressed concern that Roxane and BIPI “do not appear too separate to people outside our corporation.” (*Id.*) Beginning in or around 2003, Boehringer Ingelheim reviewed its management structure and determined that it “operate[d] in the U.S. with a variety of legal entities that do not always reflect the nature of [its] businesses,” “resulting in two sets of reporting: one in terms of legal entities and another in terms of business.” (*Id.*) In 2005, Roxane was reorganized into two separate companies, at least in part, to “[a]llign the U.S. organizations with the actual businesses.” (*Id.*)

Boehringer Ingelheim considered various options for restructuring its United States operations in connection with the 2005 reorganization, including eliminating BIC as a holding company. According to a September 2003 presentation regarding the “U.S. Business of Boehringer Ingelheim,” “there [wa]s no significant business advantage to keeping BIC, as the ‘corporate veil’ would likely be pierced in case of any litigation.” (*Id.*, ¶ 2.) BIC was ultimately retained, and continues to be the sole shareholder of BIPI and the reorganized Roxane.

D. Roxane’s Dividend Payments to BIC

From at least 1996 through 2001, Roxane’s retained earnings grew annually, and in each year significantly exceeded Roxane’s total liabilities. For example, at year-end 2001, Roxane had retained earning of over \$350 million against total liabilities of \$203 million. (*Id.*, ¶ 36) Retained earnings consistently exceeded total liabilities during this time frame even though Roxane paid dividends to BIC, including \$41 million in May 1999 and \$50 million in May 2000.

(*Id.*) In November 2002, however, *after* receiving a subpoena from the United States, Roxane deviated from its past practice and paid an unbudgeted \$320 million dividend to BIC. This dividend exceed Roxane's total net income for the five preceding years.⁴ (*Id.*)

Roxane had originally budgeted that its retained earnings for 2002 would be approximately \$402 million, against total liabilities of approximately \$144 million. However, after paying the \$320 million dividend, Roxane's retained earnings for year-end 2002 were slightly more than \$46 million, or *only one-fifth* of its total liabilities of \$320 million. (*Id.*, ¶¶ 36-40.) Boehringer Ingelheim's own guidelines provide that dividends are appropriate when a company's ratio of liabilities to equity is less than 1.5 to 1. (*Id.*) After paying the dividend to BIC, Roxane's liabilities were over *five times* greater than equity, and total liabilities continued to greatly exceed total equity through at least 2004. (*Id.*)

III. ARGUMENT

“Summary judgment is appropriate when ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.’” *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). Under this standard, and viewing “the facts in the light most favorable” to the United States, *id.* at 36, BIC and BIPI have failed to prove the case for summary judgment.

A. There Is a Triable Issue Whether BIC and BIPI Are Directly Liable

As an initial matter, BIC and BIPI claim that the United States' position that they are

⁴ Roxane's 2001 income was significantly larger than in prior years, due primarily to the sale of its palliative care drugs. This, however, does not explain the \$320 million dividend, which exceeded Roxane's income from the preceding *five* years, *including* 2001. (U.S. Resp. to BI SOF, ¶ 36.)

directly liable under the FCA “cannot be found anywhere” in the complaint and represents a “recent” and “last-ditch” change of “tactics.” (BIC and BIPI’s Memorandum of Law in Support of Their Motion for Summary Judgment (“BI Brief”), at 14 and note 6) This is incorrect. The United States’ Complaint is replete with references to the conduct of *defendants* (plural), alleging, for example, that “*they* maintained artificially inflated prices in order to maintain the spreads” on the Subject Drugs, (Complaint, ¶ 62) (emphasis supplied), that “employees at BIPI, in concert with employees of Roxane” decided to falsely inflate the AWPs on certain Roxane drugs (*id.*, ¶ 63), and that “BIC, BIPI and Roxane acted in concert together to foster, facilitate and promote the unlawful conduct alleged” (*id.* ¶19). The Complaint refers to “The Defendants’ Scheme” (*id.*, ¶ 15), and alleges a collective “deliberate manipulation of Roxane’s published prices.” (*Id.*, ¶ 45.) Likewise, in the specified counts, the United States alleges that “defendants” knowingly created and manipulated the spread, thereby violating the False Claims Act. (*Id.*, ¶¶ 70-71, 73, 76-78.)

The FCA “applies to anyone who knowingly assists in causing the government to pay claims grounded in fraud, without regard to whether that person ha[s] direct contractual relations with the government.” *United States ex rel. Riley v. St. Luke’s Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) (internal quotation omitted); *Peterson v. Weinberger*, 508 F.2d 45, 52-53 (5th Cir. 1975); *U.S. ex rel. Marcy v. Rowan Co., Inc.*, 2006 WL 2414349, *8 (E.D. La. 2006). “The FCA covers indirect mulcting of the government” and “a defendant may be liable if it operates under a policy that causes others to present false claims.” *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719, 735-36 (N.D. Ill. 2007) (internal quotation omitted); *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp.2d 25,

62-63 (D. D.C. 2007); *United States v. President and Fellows of Harvard College*, 323 F. Supp. 151, 186-87 (D. Mass 2004). As described below, there is extensive evidence supporting a finding that BIC and BIPI knowingly “assisted” and “cooperated” in Roxane’s publication of false AWPs for the Subject Drugs. This conduct subjects BIC and BIPI to liability under the FCA. *See, e.g., United States v. O’Connell*, 890 F.2d 563, 569 (1st Cir. 1989) (recognizing that under the FCA, corporations are vicariously liable for conduct of their employees, even if corporation did not benefit from the fraudulent acts); *United States v. Dynamics Research Corp.*, 2008 WL 886035, *14 (D. Mass. 2008) (same).

For Roxane’s branded generics (including Subject Drugs Roxicodone, Oramorph SR and Roxanol), BIC and BIPI’s participation in setting inflated AWPs was both formal and pervasive. A common pricing policy and procedure specified that a pricing committee, comprised of both Roxane and BIPI personnel, approved WACs and AWPs in the first instance, followed by the head of the Business Unit (Mr. Berkle) and the President and CEO of BIC (Mr. Gerstenberg). (U.S. Resp. to BI SOF, ¶¶, 51, 75, 76.) The published prices for Roxane’s branded generics were in fact approved according to this procedure. In the case of Roxicodone, a Roxane employee (Fred Duy) sent the proposed pricing and launch plan to Mr. Berkle and other BIPI employees for approval on August 12, 2000. (*Id.*) The launch plan recommended setting AWPs that were twice as high as WACs to create “favorable retail reimbursement.” In the ensuing days, Mr. Berkle asked that the approval process be speeded up, and no fewer than five BIPI employees (including Mr. Ciarelli, Mr. King, and Mr. Leonetti) reviewed and endorsed the launch plan, including several who commented on the calculation of the “average spread” and the “very favorable Pharmacy spread.” (*Id.*) On August 22, the pricing committee recommended the

prices to the head of the Business Unit (Mr. Berkle) and the President and CEO of BIC (Mr. Gerstenberg). The committee made no secret of the strategy behind setting high AWPs, which it described as “compatible with the reimbursement model that drives retailer profit.” Mr. Berkle and Mr. Gerstenberg approved the proposed prices shortly after receiving the pricing committee’s recommendation. (*Id.*)

BIC and BIPI also participated in the pricing and marketing of Roxane’s “multi-source” drugs, although through a less formal procedure. For example, BIPI employees met regularly with their Roxane counterparts regarding the launch of ipratropium bromide, including at a meeting where it was agreed that the AWP for ipratropium bromide was to be set at 10% less than Atrovent’s AWP, or approximately twice as high as the expected selling price. (*Id.*, ¶¶ 7, 53, 56, 69) Ed Tupa, then Roxane Vice President of Marketing, testified that he believed Mr. Berkle was involved in the decision to approve the ipratropium bromide marketing plan. (*Id.*) The evidence also demonstrates that BIC approved raising the AWPs for furosemide in August 2000, in spite of its awareness of government investigations. (*Id.*, ¶¶ 53, 61, 70-71) Emails sent contemporaneously with the furosemide AWP increase describe Mr. Russillo, who was then in charge of Roxane’s multi-source marketing, as willing to “champion” the increase and take the proposal “up the line.” (*Id.*) Mr. Russillo himself advised employees that in order to get the “approval” Roxane “needed” from Boehringer Ingelheim, information about competitors’ AWPs was required. Mr. Russillo testified that based on many conversations with Mr. Gerstenberg, he understood Boehringer Ingelheim approved raising AWPs on Roxane’s drugs, so long as Roxane did so to “match” competitors. (*Id.*) Mr. Russillo also testified that he would not have implemented the furosemide AWP increase unless he believed it was authorized. (*Id.*)

This conduct, on its own, is sufficient to submit BIC and BIPI to liability under the FCA.

See, e.g., President and Fellows of Harvard College, 323 F.Supp. at 186-87 (“a defendant may be liable if it operates under a policy that causes others to present false claims”). However, BIC and BIPI’s participation in the conduct at issue was not limited to the approval of inflated AWPs. Mr. Ciarelli, for example, had “ongoing responsibility” for reporting prices (including AWPs) to third-party pricing compendia for Roxane’s branded generic products, and was one of two persons responsible for ensuring that BIPI and Roxane complied with applicable laws in reporting prices. (U.S. Resp. to BI SOF, ¶ 14) Likewise, Jim Rowenhorst recommended that Roxane and BIPI “focus on higher AWP and WAC” as a way of competing with Dey Laboratories in the respiratory market. (*Id.*, ¶ 53)

In the face of this evidence, defendants claim that to establish liability under the FCA, the United States must show that BIC and BIPI were “actively involved in setting *and* publishing AWPs and WACs *for each of the nine Roxane Drugs at issue.*” (BI Brief, at 15) On the contrary. As demonstrated above, the proof of BIC and BIPI’s involvement in setting AWPs for Roxane’s drugs is extensive, and includes evidence that BIC and BIPI specifically approved AWPs for many of the Subject Drugs. Defendants cite no authority in support of their assertion that the United States must come forth with evidence that BIC and BIPI were actively involved in setting AWPs for *each* of the Subject Drugs.⁵ The evidence establishes (among other things) that

⁵ Defendants’ reliance on three prior decisions of this Court in other AWP cases (BI Brief at 15, 16) is misplaced. In the three cases, in the context of discussing whether AWPs and WACs were inflated, the Court observed that the *falsity* of prices must be established drug by drug. Whether BIC and BIPI knowingly assisted in and approved the setting of false AWPs is an altogether different issue and in any event, as demonstrated above, there is ample evidence Roxane set its reported prices in conformance with Boehringer Ingelheim policy and positions.

BIC and BIPI approved AWPs for Roxane's branded generic products pursuant to a formal pricing policy, and that Roxane officials raised AWPs for multi-source products only after understanding the Boehringer Ingelheim position that Roxane could do so provided it was matching competitors' pricing. This evidence is more than sufficient to create a triable issue as to whether BIC and BIPI knowingly assisted in setting AWPs for Roxane's products generally, or for all of the Subject Drugs. Nor, as defendants claim, is the United States required to show defendants were involved in actually "publishing" the AWPs in question; that the AWPs would be published was a foreseeable and intended consequence of the decision to set or approve the price. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 478 F.Supp.2d 164, 174-75 (D. Mass. 2007) (foreseeable events do not sever chain of causation under FCA).

Finally, BIC and BIPI contend that their employees' involvement in setting inflated AWPs for Roxane's drugs is not binding on the corporations themselves because the employees in question were acting as "agents" of Roxane. (BI Brief, at 17-19) This argument amounts to little more than a tautology, and is without factual or legal support. BIC and BIPI primarily rely on the Supreme Court's decision in *United States v. Bestfoods*, 524 U.S. 51 (1998), which holds that employees with dual roles at affiliated companies can and do "change hats" to represent the two corporations separately, and that when an employee "acts for" a subsidiary company, he is presumed to be wearing his "subsidiary hat."⁶ BIC and BIPI's reliance on *Bestfoods* is misplaced here because most of the employees in question (including Mr. Ciarelli, Mr. King, Mr. Leonetti

⁶ Defendants also purport to rely on the testimony of its "corporate governance expert," Jonathan Macey. Plainly, Mr. Macey's testimony is irrelevant to both the factual question of in what "capacity" an employee was acting when participating in Roxane's sales and marketing activities, and to the legal question of whether such conduct gives rise to liability under the FCA.

and Mr. Rowenhorst) were employed *only* by BIPI and, therefore, had no “Roxane hat” to wear.

Bestfoods expressly distinguishes between “directors and officers *holding positions* with a parent and its subsidiary” and “an agent of the parent *with no hat to wear but the parent’s hat.*” 524 U.S. at 69-71 (emphasis added). Where, as here, employees involved in the alleged wrong were employed *only* by BIPI, their actions are naturally regarded as within the scope of that employment, and are properly attributed to BIPI. *Id.*, at 64-64 (where “alleged wrong can seemingly be traced to the parent through the conduit of its own personnel and management[,]” the parent is “directly liable for its own actions”); *United States v. Kayser-Roth Corp.*, 272 F.3d 89, 103 (1st Cir. 2001) (finding parent company Kayser-Roth liable, and noting that “with no hat to wear but” Kayser-Roth’s . . . employee “acted solely on behalf of Kayser-Roth.”)

Moreover, the evidence establishes that when the aforementioned BIPI employees participated in Roxane’s pricing and marketing activities, they did so *as BIPI employees*. Specifically, employee bulletins describing the organization of the Business Unit noted that Roxane employees *reported to* their “BIPI counterparts,” indicating that when Mr. King, Mr. Ciarelli, Mr. Leonetti, etc., supervised Roxane sales and marketing efforts, they did so as BIPI employees. Likewise, when Mr. Gerstenberg approved prices for the Subject Drugs, he did so in his role as President and CEO of BIC. Although, unlike the aforementioned employees, Mr. Gerstenberg did have roles at both Roxane and BIC, the pricing policy specified that AWPs for Roxane’s branded generics required approval by the “President and CEO of BIC,” showing that when Mr. Gerstenberg approved AWPs for these products, he did so in that capacity.

B. There Is a Triable Issue Whether the Corporate Veils Should Be Pierced

The corporate veil may be pierced “if one corporation is not an independent entity, but rather the mere alter ego of another.” *Brotherhood of Locomotive Eng’rs. v. Springfield Terminal Ry. Co.*, 210 F.3d 18, 25 (1st Cir. 2000); *Escade Cruz v. Ortho Pharmaceuticals Corp.*, 619 F.2d 902, 905 (1st Cir. 1980) (“presumption of corporate separateness may be overcome by clear evidence that the parent in fact controls the activities of the subsidiary.”)⁷ The question of when to pierce the corporate veil is “notably imprecise and fact-intensive” and, therefore, is “the sort of determination usually made by a jury because it is so fact specific.” *Crane v. Green & Freedman Baking Co.*, 134 F.3d 17, 21-22 (1st Cir. 1998).

Because the United States’ claims are brought under the FCA and relate to the Medicare and Medicaid programs, federal law “controls the veil-piercing question.” *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F.Supp.2d 35, 39-40 (D. Mass. 2000); *United States ex rel. Siewick v. Jamison Science and Engineering, Inc.*, 191 F. Supp. 2d 17, 20-21 (D. D.C. 2002) (“The government’s interest in protecting itself from fraud, as embodied in the False Claims Act, makes it reasonable to apply the federal common law standard for piercing the corporate veil.”) “Under the federal common law, there is no precise litmus test for determining when the corporate form should be ignored.” *InterGen N.V. v. Grina*, 344 F.3d 134, 148 (1st Cir. 2003) (citing *Alman v. Danin*, 801 F.2d 1, 3 (1st Cir. 1986)). In general, federal courts “are not bound by the strict standards of the common law alter ego doctrine which would apply in a tort or contract action.” *Locomotive Eng’rs.*, 210 F.3d at 26. “Instead, the rule in federal cases is founded *only* on the broad principle that a corporate entity may be disregarded in the interests of

⁷ Courts pierce the corporate veil in cases involving “sibling” corporations as well as parent and subsidiary corporations. See *Locomotive Eng’rs.*, 210 F.3d at 29.

public convenience, fairness and equity.” *Id.* (emphasis supplied). In applying this rule, courts look closely to the “purpose of the federal statute,” “an inquiry that usually gives less respect to the corporate form than does the common law alter ego doctrine.” *Id.* (*citing Town of Brookline v. Gorusch*, 667 F.2d 215, 221 (1st Cir. 1981)).⁸

Factors that federal courts use in considering whether to pierce the corporate veil include, among others, (1) excessive control by shareholders, (2) intermingling of business activities or management, (3) failure to observe corporate formalities and separateness, (4) inadequate capitalization and (5) siphoning of funds from the corporation. *See, e.g., In re Acushnet River & New Bedford Harbor Proceedings*, 675 F. Supp. 22, 33 (D. Mass. 1987). Here, there is abundant evidence that BIC and BIPI ignored the corporate separateness of Roxane, and exercised pervasive control over Roxane’s business. Specifically, Roxane and BIPI were managed as part of a single business unit with overlapping management. (U.S. Resp. to BI SOF, ¶¶ 7-8, 14, 51, 53.) Numerous Roxane employees reported to their “BIPI counterparts” in sales, marketing and other departments. Moreover, from at least 1998 through 2001, neither of the senior managers in charge of Roxane’s marketing efforts were Roxane employees. (*Id.*, ¶ 14.) Roxane and BIPI also shared core business functions, such as a single contracts unit, as well as a “Trade Relations Group” responsible for promoting both Roxane and BIPI products. (*Id.*, ¶¶ 7-8, 51, 53.)

The evidence further reveals that Roxane and BIPI’s businesses were managed for the benefit of the overall Boehringer Ingelheim group of companies even, in some cases, where

⁸ A “less rigorous” veil-piercing standard applies in cases arising under various federal statutes, including ERISA, *Locomotive Eng’rs*, 210 F.3d at 27, the Clayton Act, *Stotter & Co. V. Amstar Corp.*, 579 F.2d 13, 18-19 (3rd Cir. 1978) and the Communications Act, *Capital Tel. Co. v. FCC*, 498 F.2d 734, 738 (D.C. Cir. 1974).

doing so arguably harmed the interests of one corporation at the expense of the other. Roxane and BIPI regularly submitted joint bids to customers, including bids in which rebates on BIPI products were “held back” pending customers’ commitment to purchase Roxane products as well. (*Id.*, ¶ 9.) Likewise, Roxane and BIPI utilized combined marketing strategies for certain classes of products, including inhalation therapy drugs. In the case of ipratropium bromide, for example, Roxane launched the product pre-emptively (i.e., while BIPI’s Atrovent was still patent-protected), a strategy which had no long term benefits to BIPI, but which benefitted the Boehringer Ingelheim group as a whole. (*Id.*) Consistent with this strategy, BIPI’s sales force promoted both Atrovent and Roxane’s ipratropium bromide and, when Roxane had trouble supplying ipratropium bromide, BIPI even allowed Roxane to fill orders with Atrovent instead. (*Id.*, ¶ 7) All of these factors counsel in favor of piercing Roxane’s corporate veil. *See, e.g.*, *R&R Chemicals, LLC v. Cellect, LLC*, 2002 WL 2018725, *6 (D. Mass. 2002).

Not surprisingly, several Boehringer Ingelheim employees testified that they themselves were unclear as to the corporate status of Roxane and BIPI. Judy Waterer, for instance, described Boehringer Ingelheim as “kind of an intermingled company” and noted that the corporate organization was “very jumbled” because “there are a lot of legal definitions” for what she “consider[ed] to be different branches of the company.” (U.S. Resp. to BI SOF, ¶ 12.) Likewise, John Powers (who ran the Contracts Department for Roxane and BIPI), testified that beginning in 1996, “decisions were made that the Roxane business and the Boehringer business should get closer together in terms of management, that the two companies shouldn’t be run as two separate entities any longer.” (*Id.*, ¶ 79.) Boehringer Ingelheim employees also expressed concern that Roxane and BIPI did not appear as separate companies to third parties. (*Id.*, ¶ 12.)

Perhaps most revealingly, documents created in conjunction with Boehringer Ingelheim's efforts to reorganize its United States operations in or around 2003 candidly explain that Boehringer Ingelheim "operated[d] in the U.S. with a variety of legal entities that d[id] not necessarily reflect the nature of [its] business," requiring "two sets of reporting: one in terms of legal entities and another in terms of businesses." (*Id.*) Other contemporaneous documents explained that as a result of prior organizational changes in the Business Unit, employees were crossing over between Roxane and BIPI's businesses, and that the 2005 reorganization was required "to align" employees with the businesses they served. (*Id.*)

In spite of such evidence, defendants argue they are entitled to summary judgment because "neither BIC nor BIPI intended to use Roxane's corporate form as a fraud," which defendants contend is required to pierce the corporate veil. (BI Brief, at 9, 12.)⁹ This is an incorrect statement of law and, in any event, Roxane's corporate form *is* being improperly used, as reflected by its inadequate capitalization, and the fact that BIC siphoned off Roxane's corporate assets after receiving a subpoena from the federal government.

First, defendants mistakenly rely on *United Elec., Radio & Mach. Workers v. 163 Pleasant St. Corp.*, 960 F.2d 1080 (1st Cir. 1992), for the proposition that a finding of "fraudulent intent" "is a *sine qua non* to the alter ego remedy's availability." As the First Circuit has subsequently explained, "[f]undamentally, *163 Pleasant St.* is a case about personal

⁹ Defendants also suggest that the Government does not have evidence that Roxane was *created* as a sham corporation. This is irrelevant. *See Locomotive Eng'rs.*, 210 F.3d at 30 (it "would make little sense to ignore current relationships and arrangements between corporations" and thereby grant immunity from veil piercing in those cases where the corporation was originally formed for a legitimate purpose.")

jurisdiction,” standing only for the proposition that “personal jurisdiction cannot be exercised over a foreign corporation through a corporate veil piercing theory absent a showing of fraud.” *Mass. Carpenters Central Collection Agency v. Belmont Concrete Corp.*, 139 F.3d 304, 308 (1st Cir. 1998). The First Circuit disapproves of applying “veil-piercing rules *for jurisdictional purposes*” to veil-piercing questions, and the First Circuit has held that “there is no rule that wrongful motive is an essential element of a finding of alter ego status.” *Id.* (emphasis supplied)

Second, although Roxane consistently had equity well in excess of its total liabilities from at least 1996 through 2001, that changed following Roxane’s payment of an unbudgeted \$320 million dividend to BIC in November 2002. As noted earlier, that dividend exceeded Roxane’s total income from the preceding *five years*, and was paid *after* Roxane received its first subpoena relating to its reported AWPs. (U.S. Resp. to BI SOF, ¶¶ 36, 39.) Moreover, payment of the dividend left Roxane with total liabilities over five times larger than its equity, and considerably less capitalized than many of its competitors. (*Id.*) In addition, payment of the dividend appears to have violated Boehringer Ingelheim own guidelines providing that dividends are appropriate when liabilities are less than one and half times larger than equity. (*Id.*) Such a wrongful diversion of corporate assets, on its own, justifies piercing the corporate veil. *See, e.g., United States v. Bridle Path Enterprises, Inc.*, 2001 WL 1688911, *3 (D. Mass. 2001).

IV. CONCLUSION

Accordingly, for all of the foregoing reasons, the motion by BIC and BIPI for summary judgment should be denied on grounds that there are triable issues of fact on all claims that should be permitted to proceed to trial.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: August 28, 2009

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